

molecular weight that appears to be of the order of 50, 32-35, or 30 kDa after electrophoresis on a 10% polyacrylamide gel in the presence of SDS.

2. (Canceled).

3. (Previously Amended) The composition of claim 1, wherein the apparent molecular weight of the protein is of the order of 50 kDa and the protein is obtainable by a process in which:

- (i) *H. pylori* bacteria are extracted with 1% n-octyl  $\beta$ -D glucopyranoside, followed by centrifugation;
- (ii) a bacterial pellet is recovered and it is treated with lysozyme and subjected to sonication, followed by centrifugation;
- (iii) a centrifugation pellet is recovered and it is subjected to washing with 20 mM Tris-HCl buffer pH 7.5, followed by centrifugation;
- (iv) the membrane fraction consisting of the centrifugation pellet is recovered and it is resuspended in aqueous medium;
- (v) the membrane fraction is subjected to an anion-exchange chromatography on a Q-Sepharose column in a 0-0.5 M NaCl gradient, followed by washing in 1 M NaCl;
- (vi) the fraction eluted at the start of washing in 1 M NaCl is recovered and it is subjected to an anion-exchange chromatography on a DEAE-Sepharose column, in a 0-0.5 M NaCl gradient; and
- (vii) the fraction eluted in 0.3-0.4 M NaCl is recovered.

4. (Previously Amended) The composition of claim 3, wherein the protein has as N-terminal sequence the amino acid sequence as shown in SEQ ID NO:1.

5. (Previously Amended) The composition of claim 1, wherein the apparent molecular weight of the protein is of the order of 30 kDa and the protein is obtainable by a process in which:

- (i) *H. pylori* bacteria are extracted with 1% n-octyl  $\beta$ -D glucopyranoside, followed by centrifugation;
- (ii) a bacterial pellet is recovered and it is treated with lysozyme and subjected to sonication, followed by centrifugation;
- (iii) a centrifugation pellet is recovered and it is subjected to washing with 20 mM Tris-HCl buffer pH 7.5, followed by centrifugation;
- (iv) the membrane fraction consisting of the centrifugation pellet is recovered and it is resuspended in aqueous medium;
- (v) the membrane fraction is subjected to an anion-exchange chromatography on a Q-Sepharose column in a 0-0.5 M NaCl gradient;
- (vi) the fraction eluted in 0.28-0.35 M NaCl is recovered and it is subjected to an anion-exchange chromatography on a DEAE-Sepharose column, in a 0-0.5 M NaCl gradient; and
- (vii) the fraction corresponding to the direct eluate is recovered (absence of NaCl).

6. (Previously Amended) The composition of claim 1, wherein the apparent molecular weight of the protein is of the order of 32-35 kDa and the protein is obtainable by a process in which:

- (i) *H. pylori* bacteria are extracted with 1% n-octyl  $\beta$ -D glucopyranoside, followed by centrifugation;
- (ii) a bacterial pellet is recovered and it is treated with lysozyme and subjected to sonication, followed by centrifugation;
- (iii) a centrifugation pellet is recovered and it is subjected to washing with 20 mM Tris-HCl buffer pH 7.5, followed by centrifugation;
- (iv) the membrane fraction consisting of the centrifugation pellet is recovered and it is resuspended in aqueous medium, advantageously in carbonate buffer pH 9.5;
- (v) the suspension obtained in (iv) is centrifuged at about 200,000 x g and the supernatant is recovered;
- (vi) the pH of the supernatant obtained in (v) is reduced to about pH 7, advantageously by dialysing against phosphate buffer pH 7;
- (vii) the preparation obtained in (vi) is subjected to a cation-exchange chromatography on an SP-Sepharose column in a 0 - 0.5 M NaCl gradient, advantageously in a phosphate buffer pH 7; and
- (viii) the fraction eluted in 0.26 - 0.31 M NaCl is recovered.

7. (Previously Amended) A *Helicobacter* protein, or a polypeptide that is derived from the protein by fragmentation, in a substantially purified form, which is recognized by an antiserum raised against the protein of the composition of claim 1.

8 and 9. (Canceled).

10. (Currently Amended) A composition consisting ~~essentially~~ of a monospecific antibody that recognizes the protein of the composition of claim 1.

11. (Currently Amended) A composition consisting ~~essentially~~ of a monospecific antibody that recognizes the protein or polypeptide of claim 7.

12 and 13. (Canceled).

14. (Currently Amended) A diagnostic method for detecting the presence of Helicobacter in a biological sample, ~~according to which~~ comprises bringing the biological sample ~~is brought~~ into contact with the antibody of claim 10 so that an immune complex forms, removing the unbound material ~~is removed~~, and detecting the immune complex formed between components of the sample and the antibody ~~is detected~~.

15. (Currently Amended) A diagnostic method for detecting the presence of antibodies to Helicobacter in a biological sample, ~~according to which~~ comprises bringing the biological sample ~~is brought~~ into contact with the protein or polypeptide of claim 1 or claim 7 so that an immune complex forms, removing the unbound material ~~is removed~~, and detecting the immune complex formed between components of the sample and the protein or polypeptide ~~is detected~~.

16. (Currently Amended) A process for the purification of the protein of the composition of claim 1 from a biological sample, ~~according to which~~ comprises subjecting the biological sample to affinity chromatography using a monospecific antibody that recognizes said protein or polypeptide, and eluting said protein from said monospecific antibody.

17. (Currently Amended) An isolated immunogenic polypeptide fragment of the protein of the composition of claim 1.

18. (Currently Amended) ~~A The composition of claim 1, further consisting essentially of~~ (i) a *Helicobacter pylori* protein in a pharmaceutically acceptable form, wherein said protein has a molecular weight that appears to be on the order of 50, 32-35, or 30 kDa after electrophoresis on a 10% polyacrylamide gel in the presence of SDS, and (ii) an adjuvant.

19. (Currently Amended) ~~A The composition of claim 1, further consisting essentially of~~ (i) a *Helicobacter pylori* protein in a pharmaceutically acceptable form, wherein said protein has a molecular weight that appears to be on the order of 50, 32-35, or 30 kDa after electrophoresis on a 10% polyacrylamide gel in the presence of SDS, and (ii) an additional *Helicobacter* polypeptide antigen.

20. (Currently Amended) The composition of claim 19, wherein the additional *Helicobacter* polypeptide antigen comprises a *Helicobacter* urease, or an immunogenic subunit or fragment thereof.

21. (Withdrawn).

22. (Previously Added) The composition of claim 1, wherein said *Helicobacter* membrane fraction protein has a molecular weight that appears on the order of 50 kDa after electrophoresis on a 10% polyacrylamide gel in the presence of SDS.

23. (Previously Added) The composition of claim 1, wherein said *Helicobacter* membrane fraction protein has a molecular weight that appears on the order of 32-35 kDa after electrophoresis on a 10% polyacrylamide gel in the presence of SDS.

24. (Previously Added) The composition of claim 1, wherein said *Helicobacter* membrane fraction protein has a molecular weight that appears on the order of 30 kDa after electrophoresis on a 10% polyacrylamide gel in the presence of SDS.

25-27. (Withdrawn).

28. (Previously Added) A composition consisting ~~essentially~~ of a *Helicobacter pylori* protein in a pharmaceutically acceptable form, wherein said protein has a molecular weight that appears to be of the order of 50, 32-35, or 30 kDa after electrophoresis on a 10% polyacrylamide gel in the presence of SDS.

29. (Previously Added) A composition consisting ~~essentially~~ of (i) a *Helicobacter pylori* protein having a molecular weight that appears to be of the order of 54 kDa after electrophoresis

on a 10% polyacrylamide gel in the presence of SDS, and (ii) an additional *Helicobacter* polypeptide antigen, wherein said protein and said additional *Helicobacter* polypeptide antigen are in pharmaceutically acceptable form.

30. (Canceled).

31 and 32. (Withdrawn).

33. (New) A composition consisting of (i) a *Helicobacter pylori* membrane fraction protein having a molecular weight that appears to be of the order of 50, 32-35, or 30 kDa after electrophoresis on a 10% polyacrylamide gel in the presence of SDS, and (ii) a pharmaceutically acceptable carrier or diluent, wherein said composition is in a pharmaceutically acceptable form.

34. (New) A composition consisting of (i) a *Helicobacter pylori* membrane fraction protein having a molecular weight that appears to be of the order of 50, 32-35, or 30 kDa after electrophoresis on a 10% polyacrylamide gel in the presence of SDS, (ii) an adjuvant, and (iii) a pharmaceutically acceptable carrier or diluent, wherein said composition is in a pharmaceutically acceptable form.

35. (New) A composition consisting of (i) a *Helicobacter pylori* membrane fraction protein having a molecular weight that appears to be of the order of 50, 32-35, or 30 kDa after electrophoresis on a 10% polyacrylamide gel in the presence of SDS, (ii) an additional

Helicobacter polypeptide antigen, and (iii) a pharmaceutically acceptable carrier or diluent, wherein said composition is in a pharmaceutically acceptable form.

36. (New) A composition consisting of (i) a *Helicobacter pylori* membrane fraction protein having a molecular weight that appears to be of the order of 50, 32-35, or 30 kDa after electrophoresis on a 10% polyacrylamide gel in the presence of SDS, (ii) an adjuvant, and (iii) an additional Helicobacter polypeptide antigen, wherein said composition is in a pharmaceutically acceptable form.

37. (New) A composition consisting of (i) a *Helicobacter pylori* membrane fraction protein having a molecular weight that appears to be of the order of 50, 32-35, or 30 kDa after electrophoresis on a 10% polyacrylamide gel in the presence of SDS, (ii) an adjuvant, (iii) an additional Helicobacter polypeptide antigen, and (iv) a pharmaceutically acceptable carrier or diluent, wherein said composition is in a pharmaceutically acceptable form.

38. (New) A composition consisting of (i) a *Helicobacter pylori* protein having a molecular weight that appears to be of the order of 54 kDa after electrophoresis on a 10% polyacrylamide gel in the presence of SDS, (ii) an additional Helicobacter polypeptide antigen, and (iii) a pharmaceutically acceptable carrier or diluent, wherein said composition is in a pharmaceutically acceptable form.

39. (New) A composition consisting of (i) a *Helicobacter pylori* protein having a molecular weight that appears to be of the order of 54 kDa after electrophoresis on a 10%



polyacrylamide gel in the presence of SDS, (ii) an additional *Helicobacter* polypeptide antigen, and (iii) an adjuvant, wherein said composition is in a pharmaceutically acceptable form.

40. (New) A composition consisting of (i) a *Helicobacter pylori* protein having a molecular weight that appears to be of the order of 54 kDa after electrophoresis on a 10% polyacrylamide gel in the presence of SDS, (ii) an additional *Helicobacter* polypeptide antigen, (iii) an adjuvant, and (iv) a pharmaceutically acceptable carrier or diluent, wherein said composition is in a pharmaceutically acceptable form.

41. (New) A *Helicobacter pylori* protein in a substantially purified form, wherein said protein has a molecular weight that appears to be of the order of 50, 32-35, or 30 kDa after electrophoresis on a 10% polyacrylamide gel in the presence of SDS.